

What is claimed is:

1. A sustained release pharmaceutical formulation that is capable of therapeutically effective bioavailability of guaifenesin for at least twelve hours after dosing, the formulation comprising:

- (a) guaifenesin;
- (b) a hydrophilic polymer; and
- (c) a water-insoluble polymer;

wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 1:1 to about 6:1.

2. The formulation of claim 1 wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 3:2 to about 4:1.

3. The formulation of claim 1 wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 2:1.

4. The formulation of claim 1 wherein the hydrophilic polymer is selected from the group consisting of acacia, gum tragacanth, locust bean gum, guar gum, karaya gum, modified cellulosic, methylcellulose, hydroxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethylcellulose, carboxymethylcellulose, agar, pectin, carrageen, alginate, carboxypolymethylene, gelatin, casein, zein, bentonite, magnesium aluminum silicate, polysaccharide, modified starch derivatives, and a combination thereof.

5. The formulation of claim 4 wherein the water-insoluble polymer is selected from the group consisting of polyacrylic acids, acrylic resins, acrylic latex dispersions, cellulose acetate phthalate, polyvinyl acetate phthalate, hydroxypropyl methylcellulose phthalate and a combination thereof.

6. The formulation of claim 1 wherein the hydrophilic polymer is hydroxypropyl methylcellulose and the water-insoluble polymer is an acrylic resin.

7. The formulation of claim 1 further comprising a pharmaceutical additive.

8. The formulation of claim 7 wherein the pharmaceutical additive is selected from the group consisting of magnesium stearate, calcium stearate, zinc stearate, powdered stearic acid, hydrogenated vegetable oils, talc, polyethylene glycol, mineral oil, EMERALD GREEN LAKE, an FD&C color, sucrose, lactose, gelatin, starch paste, acacia, tragacanth, povidone, polyethylene glycol, Pullulan, corn syrup, colloidal silicon dioxide, talc, sodium lauryl sulfate, dioctyl sodium sulfosuccinate, triethanolamine, polyoxyethylene sorbitan, poloxalkol, quarternary ammonium salts, mannitol, glucose, fructose, xylose, galactose, maltose, xylitol, sorbitol, potassium chloride, potassium sulfate, potassium phosphate, sodium chloride, sodium sulfate, sodium phosphate, magnesium chloride, magnesium sulfate, magnesium phosphate, microcrystalline cellulose, sodium starch glycolate, and a combination thereof.

9. The formulation of claim 7 wherein the pharmaceutical additive is a combination of magnesium stearate and EMERALD GREEN LAKE.

10. The formulation of claim 7 wherein the pharmaceutical additive is a combination of magnesium stearate and FD&C BLUE #1.

11. The formulation of claim 7 wherein about 95.5% of the formulation by weight is the guaifenesin, about 2.4% of the formulation by weight is the hydrophilic polymer, about 1.2% of the formulation by weight is the water-insoluble polymer, and about 1% of the formulation by weight is the pharmaceutical additive.

12. A modified release bi-layer tablet comprising:

- (a) an immediate release portion; and
- (b) a sustained release portion;

wherein the immediate release portion comprises guaifenesin which becomes fully bioavailable in a subject's stomach, and the sustained release portion comprises the sustained release formulation of claim 1.

13. The modified release bi-layer tablet of claim 12 wherein the C_{max} , AUC_{inf} and AUC_{0-12} are approximately directly proportional for each dosage strength.

14. A modified release bi-layer tablet comprising:

- (a) an immediate release portion; and
- (b) a sustained release portion;

wherein the immediate release portion comprises guaifenesin which becomes fully bioavailable in a subject's stomach, and the sustained release portion comprises the sustained release formulation of claim 11.

15. A modified release capsule comprising:

- (a) an immediate release portion; and
- (b) a sustained release portion;

wherein the immediate release portion comprises guaifenesin which becomes fully bioavailable in a subject's stomach, and the sustained release portion comprises the sustained release formulation of claim 11.

16. A modified release tablet having two portions, wherein a first portion is an immediate release formulation comprising:

- (a) a first quantity of guaifenesin; and
- (b) a first pharmaceutical additive;

and a second portion is a sustained release formulation comprising:

- (a) a second quantity of guaifenesin;
- (b) a hydrophilic polymer;
- (c) a water-insoluble polymer; and
- (d) a second pharmaceutical additive;

wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 1:1 to about 6:1.

17. The tablet of claim 16 wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 3:2 to about 4:1.

18. The tablet of claim 16 wherein the hydrophilic polymer and the water-insoluble polymer are in a weight ratio range of about 2:1.

19. The tablet of claim 16 wherein the first pharmaceutical additive and the second pharmaceutical additive are selected from the group consisting of magnesium stearate, calcium stearate, zinc stearate, powdered stearic acid, hydrogenated vegetable oils, talc,

polyethylene glycol, mineral oil, Emerald Green Lake, an FD&C color, sucrose, lactose, gelatin, starch paste, acacia, tragacanth, povidone, polyethylene glycol, Pullulan, corn syrup, colloidal silicon dioxide, talc, sodium lauryl sulfate, dioctyl sodium sulfosuccinate, triethanolamine, polyoxyethylene sorbitan, poloxalkol, quarternary ammonium salts, mannitol, glucose, fructose, xylose, galactose, maltose, xylitol, sorbitol, potassium chloride, potassium sulfate, potassium phosphate, sodium chloride, sodium sulfate, sodium phosphate, magnesium chloride, magnesium sulfate, magnesium phosphate, microcrystalline cellulose, sodium starch glycolate, and combinations thereof.

20. The tablet of claim 16 wherein the hydrophilic polymer is hydroxypropyl methylcellulose.

21. The tablet of claim 20 wherein the water insoluble polymer is an acrylic resin.

22. The tablet of claim 21 wherein a ratio of the second quantity of guaifenesin to the first quantity of guaifenesin is 5:1.

23. The tablet of claim 20 wherein a ratio of the second quantity of guaifenesin to the first quantity of guaifenesin is about 5:1.

24. The tablet of claim 23 wherein the first pharmaceutical additive is a combination of microcrystalline cellulose, sodium starch glycolate, and magnesium stearate, and the second pharmaceutical additive is a combination of magnesium stearate and Emerald Green Lake.

25. A modified release tablet comprising guaifenesin wherein the tablet demonstrates a C_{max} equivalent to an immediate release guaifenesin tablet and wherein the tablet is capable of providing therapeutically effective bioavailability of guaifenesin for at least twelve hours after dosing in a human subject according to serum analysis.

26. The tablet of claim 25 wherein the guaifenesin is in a quantity of 1200 mg.

27. The tablet of claim 26 wherein the C_{max} of said tablet is from about 1600 to 2500 µg/mL and said tablet has an AUC_{inf} of from about 5600 to 8750 hr*µg/mL.

The tablet of claim 27 wherein the C_{max} of said tablet has an AUC_{inf} of at least $7000 \text{ hr} \cdot \mu\text{g/mL}$.

The tablet of claim 25 wherein the guaifenesin is in the form of a tablet.

The tablet of claim 29 wherein the C_{max} of said tablet has an AUC_{inf} of from about 2800 to about $7000 \text{ hr} \cdot \mu\text{g/mL}$.

The tablet of claim 30 wherein the C_{max} of said tablet has an AUC_{inf} of at least $3500 \text{ hr} \cdot \mu\text{g/mL}$.

The tablet of claim 25 wherein said tablet has a $t_{1/2}$ of at least 3 hours.

5

d tablet has a
 tablet of claim
 MIC of

10

2

add
A)

add
R5